

REMARKS

Claims 1-3, 6-11 and 15-26 are pending in this application.

The instant Office Action rejects Claims 1-3, 6-11 and 15-26 (a Final Rejection). The Examiner asserts that the new ground(s) of rejection were necessitated by the amendments of 3/29/05 and that as such, a final rejection is warranted. Applicant disagrees that the new grounds of rejection were necessitated by these amendments, but since this is the fourth substantive Office Action in this case, with the Examiner in each instance citing new references (whether or not claims were added), Applicant accepts this as a final rejection and if allowance is not forthcoming based upon this response, will pursue its remedies on appeal.

As discussed below, attached is a Declaration Under 37 CFR § 1.132 By Dr. Keith H. Johnson, who in addition to being the Applicant herein, is a Professor Emeritus of Materials Science at the Massachusetts Institute of Technology and a qualified expert in the field of this invention. The submittal of this Declaration is clearly timely and should be entered since it is being submitted with this first reply after final objection for purposes of overcoming a new ground of rejection.

35 U.S.C.102 (e) Rejections

Applicant respectfully traverses the rejections (1) of Claims 1-3, 6-11 and 15-20 under 35 U.S.C. 102 (e) as being anticipated by either **Roessler et al.** (PGPUB 2002/0155084) and (2) of Claims 11, 15-18, 21 and 26 under 35 U.S.C. 102 (e) as being anticipated by **Ying et al.** (6,413,489). A 35 U.S.C. 102 rejection requires that each the reference disclose each and every limitation of the claims in issue. While Applicant

recognizes that in appropriate cases, such disclosure may be inherently present in a prior art reference and a claim or claims be properly rejected under 35 U.S.C. 102, the Examiner has not made a prima facie showing (as required by MPEP § 2112) of an appropriate rationale or provided evidence that the limitations of the rejected claims are inherently disclosed, particularly since the patent rules, MPEP and case law make it clear that such inherent disclosures be "necessarily present" and not merely "possibly" present.

Roessler et al.

Turning first to the rejections of (i) Claims 1-3, 6-11 and 15-20 under 35 U.S.C. 102 (e) as being anticipated by **Roessler et al.**, the Examiner apparently recognizes that the reference does not explicitly disclose the limitations as set forth in the instant composition and process claims, but is alleging that surfactants inherently provide the instantly claimed water structures, focusing only on this specific limitation of the claims in isolation. The Examiner correctly points to U.S. 5,800,576 (which was explicitly incorporated by reference in this application) and express portions of this application which state that specified surfactants can be used to produce these water structures. But the production of such water structures is not the invention claimed herein -- such water cluster structures and the use thereof in combustion applications is known, as acknowledged in the application as filed. Applicant does not dispute that the use of specified surfactants to produce such water cluster structures is known. But it is not any surfactant, or any composition containing appropriate surfactants, with any amounts of water and/or any type of "oil" (the other components) that produces these clusters as claimed in this application.

Roessler et al nowhere teaches or suggests that such water cluster structures are produced or even desired in the practice of its teachings, and there is no specific teaching of any process or composition that is inherently either the process or composition as claimed herein. Importantly, the Examiner has not cited any teaching of **Roessler et al** in which the instantly claimed process or composition herein, including the components which form the specified water-in-oil emulsion (i.e.; the specified amount of water, the specified amount of cosmetic or pharmaceutical oil and the specified amounts of specified surfactants or process for the delivery thereof are taught) in which the alleged formation of the specified water clusters would inherently present. As stated in the attached Declaration by Dr. Keith M. Johnson, no such teaching is made in **Roessler et al**.

One skilled in the art might equally likely from the teachings of **Roessler et al**. to be directed to form oil-in water emulsions (as taught at 0072); might be directed to select a surfactant mixture of any of the diverse surfactant-chemical compositions in Table 1 based the suggested importance low and high hydrophilic-lipophilic balance values (HBL value) (e.g.; based upon the reference's discussion at 0077 to 0086 and the list of about 100 diverse surfactant-chemical compositions in Table 1, including and their individual HBL values), etc. It is not sufficient that one skilled in the art practicing this reference "might" inherently form the water-in-oil water cluster compositions as claimed herein, by a "proper" (with the benefit of the teaching of this invention) selection of the amount of water, the type and amount of surfactant and the amount of cosmetic or pharmaceutical oil, particularly since the formation of these specified water cluster compositions is not taught in the reference or even mentioned. As is well recognized, the fact

that a certain characteristic may occur or be present in the prior art is not sufficient to establish the inherency of result or characteristic. See MPEP §2112 IV and the cases cited therein.

Further, there is now evidence that alleged inherent teaching is not made in this reference. As a result of his review of the reference and his technical expertise in this field, Dr. Johnson declares in his attached Declaration that the **Roessler et al.** does not disclose any specific formulations of water, cosmetic or pharmaceutical oil and surfactant as set forth in the rejected claim which would inherently contain water clusters as specified in the rejected claims.

However even apart from any substantive basis for rejection, it is important to note that **Roessler et al** was published on **October 24, 2002**, on an application filed **May 30, 2001**, Ser. No. 09/867,930. The instant application was filed **September 14, 2000**, which pre-dates the reference's filing date. Thus any teaching in this **Roessler et al** application is not prior art to the above-identified application. The cited teachings are from portions of the publication and the Examiner has not alleged whether these teachings (and certainly has not pointed to any) are also present in the Provisional Application No.60/208,726, filed **June 2, 2000**, referenced therein.

Furthermore a review on 6/23/05 of the USPTO database (see Exhibit A hereto) confirms that Ser. No. 09/867,930 is abandoned. As set forth in MPEP S 901.02, "... a patent application published under 35 U.S.C. 122(b) is available as prior art under 35 USC 102(e) as of the earliest effective filing date of the published application against U.S. applications filed **on or after November 29, 2000** ... (Emphasis added)". Since the instant application was filed before November 29, 2000, **Roessler et al** is not prior art

against it.

Accordingly for each of the above reasons, the rejections (1) of Claims 1-3, 6-11 and 15-20 under 35 U.S.C. 102 (e) as being anticipated by **Roessler et al.** is in error. Withdrawal of this rejection is respectfully requested.

Ying et al.

Applicant also respectfully traverses the rejection of Claims 11, 15-18, 21 and 26 under 35 U.S.C. 102 (e) as being anticipated by **Ying et al.** (6,413,489). The Examiner alleges that **Ying et al.** discloses, "a water-in-oil nanoemulsions containing at least 5% water, trimethylpentane (hydrocarbon oil), a surfactant (polyethoxylated alcohol surfactant and a cosurfactant (1-pentanol" in its example 1 and Table 1. The Examiner does not (can not properly) state that **Ying et al** explicitly discloses or alleges production the claimed water structures as recited in each of the instant claims. Instead the Examiner alleges that **Ying et al.** inherently produces these water structures. This rejection and the Examiner's basis for it are unfounded.

Ying et al.'s above teaching is not of a composition or process as set forth in the rejected claims, which is a necessary predicate for the inherency issue (as the form of the claimed water structures) to even arise. For example, each of the rejected claims *inter alia* specifies a oil formulation "selected from the group consisting of cosmetic and pharmaceutical oils"). As set forth in the attached Declaration by Dr. Keith M. Johnson, trimethylpentane is not a cosmetic or pharmaceutical oil. Instead, it is used in the petroleum and gasoline industry; it is

listed as both a hazardous air pollutants substance under the Federal Clean Air Act and a hazardous substance under the Federal Superfund Act and its hazardous properties would preclude use in cosmetic or pharmaceutical application. As further demonstration of this, as noted in the Exhibit B, (attached hereto) which is a 8/10/04 Material Safety Data Sheet for trimethylpentane which shows that this material causes significant ingestion and skin contact health and as reported in the Exhibit C, (attached hereto) which a April 1992 U.S. States Environmental Protection Agency incident report, which shows that trimethylpentane caused necrosis of the skin and tissue requiring surgery.

Further, there is now evidence that alleged inherent teaching is not made in this reference. As a result of his review of the reference and his technical expertise in this field, Dr. Johnson further declares that the **Ying et al.** composition is not a composition as claimed in the above-identified application.

Accordingly for each of the above reasons, the rejections of Claims 11, 15-18, 21 and 26 under 35 U.S.C. 102 (e) as being anticipated by **Ying et al.** is improper; Withdrawal of these rejections is also respectfully requested.

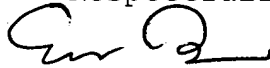
SUMMARY

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action in accordance thereof is requested.

In the event there is any reason why the application cannot be allowed in this current condition, it is respectfully requested that the Examiner contact the undersigned at the number listed

below to resolve any problems by Interview or Examiner's
Amendment.

Respectfully Submitted,

A handwritten signature in dark ink, appearing to read 'Eugene Berman', with a stylized flourish at the end.

Eugene Berman
Reg. No. 22,587

Date: July 5, 2005

Eugene Berman
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Law Offices of Eugene Berman

26 Cedarwood Court
Rockville, MD 20852

July 5, 2005

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: Response to Office Action U.S. Patent Application Serial No. 09/662,195

Gentleman/Ladies:

Enclosed is a response (Request For Reconsideration, including Exhibits A, B and C) to the Office Action dated June 8, 2005 and a Declaration Under Rule 37 CFR § 1.132 in the above-identified patent application. Please acknowledge your receipt of this response and declaration by date stamping and returning the enclosed postage paid postcard receipt.

If there are any questions, please contact me.

Very truly yours,

Eugene Berman
Reg. No. 22,587



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09/867,930 Nanoemulsion formulations

Application Data	Transaction History	Image File Wrapper	Continuity Data	Published Documents	Publication Dates	Address & Attorney/Agent
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Date	Contents Description
10-04-2004	Mail Abandonment for Failure to Respond to Office Action
09-30-2004	Abandonment for Failure to Respond to Office Action
09-20-2004	Case Docketed to Examiner in GAU
02-03-2004	Reference capture on IDS
01-26-2004	Notice of Appeal Filed
01-26-2004	Request for Extension of Time - Granted
10-17-2003	Mail Advisory Action (PTOL - 303)
10-16-2003	Advisory Action (PTOL-303)
09-15-2003	Information Disclosure Statement (IDS) Filed
09-28-2003	Date Forwarded to Examiner
09-15-2003	Amendment after Final Rejection
07-15-2003	Mail Final Rejection (PTOL - 326)
07-14-2003	Final Rejection
05-06-2003	Date Forwarded to Examiner

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05-01-2003	Response after Non-Final Action
05-01-2003	New or Additional Drawing Filed
04-21-2003	Information Disclosure Statement (IDS) Filed
01-13-2003	Mail Non-Final Rejection
01-10-2003	Non-Final Rejection
11-03-2002	Date Forwarded to Examiner
10-30-2002	Response to Election / Restriction Filed
09-26-2002	Mail Restriction Requirement
09-25-2002	Requirement for Restriction / Election
05-16-2002	X-Pre-Legal Complete New Case
04-25-2002	Application Dispatched from OIPE
04-24-2002	Application Is Now Complete
03-22-2002	Additional Application Filing Fees
03-22-2002	A set of symbols and procedures, provided to the PTO on a set of computer listings, that describe in
04-18-2002	CRF Is Good Technically / Entered into Database
01-23-2002	SEQUENCE ERRORS
01-23-2002	Pre-Exam Office Action Withdrawn
01-14-2002	Application Made Unavailable for Examination
12-14-2001	Case Docketed to Examiner in GAU
11-09-2001	Application Dispatched from OIPE
11-08-2001	Application Is Now Complete
07-26-2001	Notice Mailed--Application Incomplete--Filing Date Assigned
07-26-2001	Correspondence Address Change
06-07-2001	IFW Scan & PACR Auto Security Review
05-30-2001	Initial Exam Team nn

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MSDS Number: **T6526** * * * * * Effective Date: **08/10/04** * * * * * Supersedes: **11/12/01****EXHIBIT**

tabbies

B**MSDS****Material Safety Data Sheet**

From: Mallinckrodt Baker, Inc.
222 Rod School Lane
Phillipsburg, NJ 08865



Mallinckrodt
CHEMICALS



24 Hour Emergency Telephone: 909-659-2151
CHEMTREC: 1-800-424-6300

National Response in Canada
CANUTEC: 613-996-6666

Outside U.S. and Canada
Chemtrec: 703-527-3887

NOTE: CHEMTREC, CANUTEC and National Response Center emergency numbers to be used only in the event of chemical emergencies involving a spill, leak, fire, exposure or accident involving chemicals.

All non-emergency questions should be directed to Customer Service (1-800-582-2537) for assistance.

2,2,4-TRIMETHYLPENTANE

1. Product Identification

Synonyms: iso-octane; isobutyltrimethylmethane

CAS No.: 540-84-1

Molecular Weight: 114.23

Chemical Formula: (CH₃)₃CCH₂CH(CH₃)₂

Product Codes:

J.T. Baker: 9335, 9478, 9479, 9480, W898

Mallinckrodt: 1943, 5633, 6043, 6051, 6052, V559

2. Composition/Information on Ingredients

Ingredient	CAS No	Percent	Hazardous
Pentane, 2,2,4-trimethyl-	540-84-1	99 - 100%	Yes

3. Hazards Identification

Emergency Overview

DANGER! EXTREMELY FLAMMABLE LIQUID AND VAPOR. VAPOR MAY CAUSE FLASH FIRE. HARMFUL OR FATAL IF SWALLOWED. HARMFUL IF INHALED. CAUSES IRRITATION TO SKIN, EYES AND RESPIRATORY TRACT. AFFECTS CENTRAL NERVOUS SYSTEM.

SAF-T-DATA^(tm) Ratings (Provided here for your convenience)

Health Rating: 2 - Moderate

Flammability Rating: 3 - Severe (Flammable)

Reactivity Rating: 1 - Slight

Contact Rating: 3 - Severe (Life)

Lab Protective Equip: GOGGLES & SHIELD; LAB COAT & APRON; VENT HOOD; PROPER GLOVES; CLASS B EXTINGUISHER

Storage Color Code: Red (Flammable)

Potential Health Effects

Inhalation:

May cause symptoms similar to those of ingestion. High concentrations may cause dizziness, lack of coordination, and narcosis. Concentrations of about 16,000 ppm may cause respiratory arrest.

Ingestion:

May cause nausea, vomiting, pulmonary irritation, edema, bloody sputum, and bronchial pneumonia with fever and coughing when aspirated. If large doses (> 1ml/kg) are ingested and retained symptoms of central nervous system depression may occur and include shallow respiration, unconsciousness, and convulsions. May cause ventricular fibrillation, kidney, liver and bone marrow damage.

Skin Contact:

Causes skin irritation. May cause an allergic dermatitis.

Eye Contact:

Causes irritation; symptoms including redness, itching, and pain.

Chronic Exposure:

Prolonged or repeated skin contact may cause dermatitis.

Aggravation of Pre-existing Conditions:

Persons with pre-existing skin disorders or impaired pulmonary function may be more susceptible to the effects of this substance.

4. First Aid Measures

Inhalation:

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

Ingestion:

Aspiration hazard. If swallowed, DO NOT INDUCE VOMITING. Give large quantities of water. Never give anything by mouth to an unconscious person. Get medical attention immediately.

Skin Contact:

Remove any contaminated clothing. Wash skin with soap or mild detergent and water for at least 15 minutes. Wash clothes before reuse. Get medical attention if irritation develops or persists.

Eye Contact:

Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.

5. Fire Fighting Measures

Fire:

Flash point: -12C (10F) CC

Autoignition temperature: 415C (779F)

Flammable limits in air % by volume:

lcl: 1.1; ucl: 6.0

Extremely Flammable Liquid and Vapor! Vapor may cause flash fire.

Explosion:

Above flash point, vapor-air mixtures are explosive within flammable limits noted above. Vapors can flow along surfaces to distant ignition source and flash back. Sealed containers may rupture when heated. Contact with strong oxidizers may cause fire. Sensitive to static discharge.

Fire Extinguishing Media:

Dry chemical, foam or carbon dioxide. Water may be ineffective. Water spray may be used to keep fire exposed containers cool.

Special Information:

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode. This highly flammable liquid must be kept from sparks, open flame, hot surfaces, and all sources of heat and ignition.

6. Accidental Release Measures

Ventilate area of leak or spill. Remove all sources of ignition. Wear appropriate personal protective equipment as specified in Section 8. Isolate hazard area. Keep unnecessary and unprotected personnel from entering. Contain and recover liquid when possible. Use non-sparking tools and equipment. Collect liquid in an appropriate container or absorb with an inert material (e. g., vermiculite, dry sand, earth), and place in a chemical waste container. Do not use combustible materials, such as saw dust. Do not flush to sewer! Have foam or dry powder extinguisher on hand. Small spills will evaporate. If a leak or spill has not ignited, use water spray to disperse the vapors, to protect personnel attempting to stop leak, and to flush spills away from exposures.

J. T. Baker SOLUSORB® solvent adsorbent is recommended for spills of this product.

7. Handling and Storage

Protect against physical damage. Store in a cool, dry well-ventilated location, away from any area where the fire hazard may be acute. Outside or detached storage is preferred. Separate from incompatibles. Containers should be bonded and grounded for transfers to avoid static sparks. Storage and use areas should be No Smoking areas. Use non-sparking type tools and equipment, including explosion proof ventilation. Containers of this material may be hazardous when empty since they retain product residues (vapors, liquid); observe all warnings and precautions listed for the product. Do Not attempt to clean empty containers since residue is difficult to remove. Do not pressurize, cut, weld, braze, solder, drill, grind or expose such containers to heat, sparks, flame, static electricity or other sources of ignition: they may explode and cause injury or death.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:

- OSHA Permissible Exposure Limit (PEL): 500 ppm (TWA) for (Petroleum Distillates)
- NIOSH (REL): 10Hr.TWA, 350mg/m³, 1800 mg/m³ 15min. Ceiling for (Refined Petroleum Distillates)
- ACGIH Threshold Limit Value (TLV): 300 ppm (TWA) for (iso-octane).

Ventilation System:

A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.

Personal Respirators (NIOSH Approved):

For conditions of use where exposure to the substance is apparent and engineering controls are not feasible, consult an industrial hygienist. For emergencies, or instances where the exposure levels are not known, use a full-facepiece positive-pressure, air-supplied respirator. WARNING: Air purifying respirators do not protect workers in oxygen-deficient atmospheres.

Skin Protection:

Wear impervious protective clothing, including boots, gloves, lab coat, apron or coveralls, as appropriate, to prevent skin contact.

Eye Protection:

Use chemical safety goggles. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Appearance:

Clear, colorless liquid.

Odor:

Gasoline-like odor.

Solubility:

Negligible.

Density:

0.69 @ 20/4 C

pH:

No information found.

% Volatiles by volume @ 21C (70F):

100

Boiling Point:

99C (210F)

Melting Point:

-107C (-161F)

Vapor Density (Air=1):

3.9

Vapor Pressure (mm Hg):

ca. 41 @ 21C (70F)

Evaporation Rate (BuAc=1):

< 1 (Ether = 1)

10. Stability and Reactivity

Stability:

Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products:

Carbon dioxide and carbon monoxide may form when heated to decomposition.

Hazardous Polymerization:

Will not occur.

Incompatibilities:

Strong oxidizing agents, strong reducing agents, strong acids or bases.

Conditions to Avoid:

Heat, flames, ignition sources and incompatibles.

11. Toxicological Information

No LD50/LC50 information found relating to normal routes of occupational exposure.

Investigated as a mutagen.

-----\Cancer Lists\-----			
Ingredient	---NTP Carcinogen---		IARC Category
	Known	Anticipated	
Pentane, 2,2,4-trimethyl- (540-84-1)	No	No	None

12. Ecological Information

Environmental Fate:

When released into the soil, this material may biodegrade to a moderate extent. When released into the soil, this material is not expected to leach into groundwater. When released into the soil, this material is expected to quickly evaporate. When released into water, this material may biodegrade to a moderate extent. When released to water, this material is expected to quickly evaporate. When released into the water, this material is expected to have a half-life of less than 1 day. This material may bioaccumulate to some extent. When released into the air, this material is expected to be readily degraded by reaction with photochemically produced hydroxyl radicals. When released into the air, this material is not expected to be degraded by photolysis. When released into the air, this material is expected to have a half-life between 1 and 10 days.

Environmental Toxicity:

No information found.

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be handled as hazardous waste and sent to a RCRA approved incinerator or disposed in a RCRA approved waste facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

Domestic (Land, D.O.T.)

Proper Shipping Name: OCTANES

Hazard Class: 3

UN/NA: UN1262

Packing Group: II

Information reported for product/size: 313LB

International (Water, I.M.O.)

Proper Shipping Name: OCTANES

Hazard Class: 3

UN/NA: UN1262

Packing Group: II

Information reported for product/size: 313LB

15. Regulatory Information

-----\Chemical Inventory Status - Part 1\-----				
Ingredient	TSCA	EC	Japan	Australia
Pentane, 2,2,4-trimethyl- (540-84-1)	Yes	Yes	Yes	Yes

-----\Chemical Inventory Status - Part 2\-----				
Ingredient	Korea	DSL	NDSL	Phil.
Pentane, 2,2,4-trimethyl- (540-84-1)	Yes	Yes	No	Yes

-----\Federal, State & International Regulations - Part 1\-----				
Ingredient	-SARA 302-	TPQ	-----SARA 313-----	
Pentane, 2,2,4-trimethyl- (540-84-1)	No	No	No	No

-----\Federal, State & International Regulations - Part 2\-----				
Ingredient	CERCLA	-RCRA-	-TSCA-	
Pentane, 2,2,4-trimethyl- (540-84-1)	1000	261.33	8 (d)	

Chemical Weapons Convention: No TSCA 12(b): No CDTA: No
 SARA 311/312: Acute: Yes Chronic: No Fire: Yes Pressure: No
 Reactivity: No (Pure / Liquid)

Australian Hazchem Code: 3[Y]E

Poison Schedule: None allocated.

WHMIS:

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. Other Information

NFPA Ratings: Health: 2 Flammability: 3 Reactivity: 0

Label Hazard Warning:

DANGER! EXTREMELY FLAMMABLE LIQUID AND VAPOR. VAPOR MAY CAUSE FLASH FIRE. HARMFUL OR FATAL IF SWALLOWED. HARMFUL IF INHALED. CAUSES IRRITATION TO SKIN, EYES AND RESPIRATORY TRACT. AFFECTS CENTRAL NERVOUS SYSTEM.

Label Precautions:

Keep away from heat, sparks and flame.
 Keep container closed.
 Use only with adequate ventilation.
 Avoid breathing vapor or mist.
 Avoid contact with eyes, skin and clothing.

Wash thoroughly after handling.

Label First Aid:

Aspiration hazard. If swallowed, DO NOT INDUCE VOMITING. Give large quantities of water. Never give anything by mouth to an unconscious person. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. In all cases call a physician.

Product Use:

Laboratory Reagent.

Revision Information:

No Changes.

Disclaimer:

Mallinckrodt Baker, Inc. provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. MALLINCKRODT BAKER, INC. MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, MALLINCKRODT BAKER, INC. WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.

Prepared by: Environmental Health & Safety

Phone Number: (314) 654-1600 (U.S.A.)



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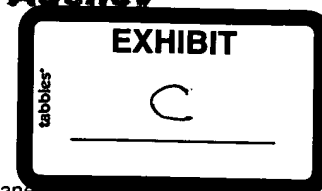
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2,2,4-Trimethylpentane

540-84-1



Hazard Summary-Created in April 1992

2,2,4-Trimethylpentane is released to the environment through the manufacture, use, and disposal of products associated with the petroleum and gasoline industry. During an accident, 2,2,4-trimethylpentane penetrated the skin of a human which caused necrosis of the skin and tissue in the hand and required surgery. No other information is available on the acute (short-term) effects in humans. Irritation of the lungs, edema, and hemorrhage have been reported in rodents acutely exposed by inhalation and injection. No information is available on the chronic (long-term), reproductive, developmental, or carcinogenic effects of 2,2,4-trimethylpentane in humans. Kidney and liver effects have been observed in rats chronically exposed via gavage (experimentally placing the chemical in the stomach) and inhalation. EPA has not classified 2,2,4-trimethylpentane with respect to potential carcinogenicity.

Please Note: The main sources of information for this fact sheet are the Hazardous Substances Data Bank (HSDB), a database of summaries of peer-reviewed literature, and Patty's Industrial Hygiene and Toxicology.

Uses

- 2,2,4-Trimethylpentane is used in determining octane numbers of fuels, in spectrophotometric analysis, as a solvent and thinner, and in organic syntheses. (1,4)

Sources and Potential Exposure

- 2,2,4-Trimethylpentane is released to the environment through the manufacture, use, and disposal of products associated with the petroleum and gasoline industry. Automotive exhaust and evaporative emissions are important sources of 2,2,4-trimethylpentane. The general public may be exposed by the inhalation of ambient air. (1)
- Occupational exposure may occur by inhalation during the refining of petroleum and during the use and disposal of petroleum products and gasoline. (1)

Assessing Personal Exposure

- No information was located regarding the measurement of personal exposure to 2,2,4-trimethylpentane.

Health Hazard Information

Acute Effects:

- During an accident, 2,2,4-trimethylpentane penetrated the skin of a human which caused necrosis of the skin and tissue in the hand and required surgery. No other information is available on the acute effects in humans. (1)
- Irritation of the lungs, edema, and hemorrhage have been reported in rodents acutely exposed by inhalation and injection. (1,2)
- Central nervous system (CNS) depression has been reported in mice following acute inhalation exposure. (1)

Chronic Effects (Noncancer):

- No information is available on the chronic effects of 2,2,4-trimethylpentane in humans.
- Kidney and liver effects have been observed in rats chronically exposed via gavage and inhalation. (1)
- EPA has not established a Reference Concentration (RfC) or a Reference Dose (RfD) for 2,2,4-trimethylpentane. (3)

Reproductive/Developmental Effects:

- No information is available on the reproductive or developmental effects of 2,2,4-trimethylpentane in humans or animals.

Cancer Risk:

- No information is available on the carcinogenic effects of 2,2,4-trimethylpentane in humans or animals.
- EPA has not classified 2,2,4-trimethylpentane with respect to potential carcinogenicity. (3)

Physical Properties

- A common synonym for 2,2,4-trimethylpentane is isooctane. (4)
- The chemical formula for 2,2,4-trimethylpentane is C_8H_{18} , and its molecular weight is 114.22 g/mol. (4)
- 2,2,4-Trimethylpentane occurs as a colorless, highly flammable, mobile liquid that is practically insoluble in water. (1,4)
- 2,2,4-Trimethylpentane smells like gasoline; the odor threshold has not been established. (1,4)
- The vapor pressure for 2,2,4-trimethylpentane is 40.6 mm Hg at 21 °C. (1,2)

Note: There are very few health or regulatory/advisory numbers for 2,2,4-trimethylpentane, thus a graph has not been prepared for this compound. The health information cited in this factsheet was obtained in December 1999.

Conversion Factors:

To convert concentrations in air (at 25 °C) from ppm to mg/m^3 : $mg/m^3 = (ppm) \times (molecular\ weight\ of\ the\ compound)/(24.45)$. For 2,2,4-trimethylpentane: 1 ppm = 4.67 mg/m^3 .

References

1. U.S. Department of Health and Human Services. Hazardous Substances Data Bank (HSDB, [online database](#)). National Toxicology Information Program, National Library of Medicine, Bethesda, MD. 1993.
2. G.D. Clayton and F.E. Clayton, Eds. *Patty's Industrial Hygiene and Toxicology*. Volume IIB. 3rd revised ed. John Wiley & Sons, New York. 1981.
3. U.S. Environmental Protection Agency. *Integrated Risk Information System (IRIS) on 2,2,4-Trimethylpentane*. National Center for Environmental Assessment, Office of Research and Development, Washington, DC. 1999.
4. *The Merck Index. An Encyclopedia of Chemicals, Drugs, and Biologicals*. 11th ed. Ed. S. Budavari. Merck and Co. Inc., Rahway, NJ. 1989.

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Last updated on Tuesday, February 22nd, 2005
URL: <http://www.epa.gov/ttn/atw/hlthef/tri-pent.html>



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.: 09/662,195

Confirmation No. 2403

Applicant: Keith Johnson

Filed: September 14, 2000

Examiner: S. Gollamudi

For: APPLICATION OR WATER NANOCCLUSERS TO SKIN

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on 5 July 2005.

(Signature)

THOMAS S. SCHILLER

(Typed or printed name of the person signing the certificate)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR §1.132 BY DR. KEITH H. JOHNSON

Sir:

I, Dr. Keith H. Johnson, do declare:

1. I am a Professor Emeritus of Materials Science at the Massachusetts Institute of Technology with which I have been affiliated since 1967..
2. I am a graduate of Princeton University with an undergraduate degree in

Physics and of Temple University with a Ph.D degree in Physics.

3. I have over 6 years of experience in the physics and chemistry of nano-emulsions and their application to cosmetics and pharmaceuticals.
4. I am the applicant in the above-identified application.
5. I have carefully read said application as originally filed and as currently amended, the Office Action therein dated June 8, 2005 and the cited prior art, including (i) USP 6,413,489 to Ying et al. (hereinafter Ying *et al.*) cited in the rejection of Claims 11, 15-18, 21 and 26 under 35 U.S.C. 102 (e) and (ii) PGPUB 20002/0155084 by Roessler *et al.* (hereinafter Roessler *et al.*) cited in the rejection of Claims 1-3, 6-11 15-25 under 35 U.S.C. 102 (e).
6. The invention disclosed and claimed the above-identified application as set forth in the rejected claims, relates to a water-in-oil nano-emulsion composition comprised of specified amounts of water containing water nanoclusters of specified configuration, specified amounts of cosmetic and pharmaceutical oils and specified amount of specified surfactants.
7. Ying *et al.* discloses a composition containing water, trimethylpentane, polyethoxylated alcohol surfactant and 1-pentanol in example 1 and Table 1.
8. The trimethylpentane component of the above-described Ying *et al.* composition is (i) used in the petroleum and gasoline industry, (ii) it is listed as both a hazardous air pollutants substance under the Federal Clean Air Act and a hazardous substance under the Federal Superfund Act, (iii) it is not used in cosmetic or pharmaceutical applications, (iv) it can cause significant adverse

health effects upon inhalation, ingestion, skin contact or eye contact and (v) its hazardous properties would preclude use in cosmetic or pharmaceutical applications.

9. The trimethylpentane component of the above-described Ying *et al.* composition may be termed is a hydrocarbon oil but it is not a cosmetic oil or a pharmaceutical oil.
10. The above described the above-described Ying *et al.* composition is not a composition as claimed in the above stated rejected claims in the above-identified application.
11. Roessler *et al.* discloses a broad array of nano emulsions, some of which may be water-in-oil emulsions and other may be water-in-oil emulsions, utilizing a broad array of compositional constituents which could result in significantly varying structural forms of water in the resultant specific formulation.
12. Roessler *et al.* does not disclose any specific formulations of water, cosmetic or pharmaceutical oil and surfactant as set forth in the rejected claim which would inherently contain water clusters as specified in the rejected claims.
13. I hereby declare that all statements made herein by my own knowledge are true and that all statements made on information and belief are believed to be true and further that I made these statement with the full knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements my jeopardize the validity of the application or any patent issuing

thereon.

Date 6/29/05

A handwritten signature in black ink, appearing to read "K. M. Johnson", written over a horizontal line.

Dr. Keith M. Johnson